

## **REMARKS**

All of pending claims 42-46 are amended. With this response, claims 42-46 remain pending.

Applicants do not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account No. 01-2508/11899.0155.DVUS02/BNT.

### **I. Oath / Declaration**

The Examiner indicated that the oath or declaration is defective, and that a new oath or declaration identifying this application by application number and filing date is required. The previously filed declaration allegedly contained incomplete or incorrect information regarding applications from which priority was claimed.

The instant application is a divisional of previously filed U.S. Patent Application Serial No. 09/313,123. Applicants included copies of the declarations executed by the inventors in the previously filed application (Serial No. 09/313,123) when filing the instant application. Applicants note that the Updated Filing Receipt appears to indicate the correct domestic priority data.

MPEP 602.05(a) and 37 CFR 1.63(d)(1)(iv) indicate that a continuation or divisional application may be filed with a copy of the oath or declaration from the prior nonprovisional application. Applicants have complied with this requirement, and respectfully asks for further clarification from the Examiner as to why a new declaration is required for this divisional application.

## **II. Objections to the specification**

1. The specification is objected to as allegedly containing an abstract that is not specifically directed to the claimed subject matter, and for being too lengthy.

Applicants note that the abstract was copied from the parent application, as the instant application is a divisional application. The abstract was found to be acceptable by the previous Examiner, and was contained in issued U.S. Patent Nos. 5,958,745 and 5,942,660. However, in addressing the Examiner's concerns, a substitute abstract is included in this response.

2. The specification was also objected to, as the first line of the specification as amended on August 30, 2001 should indicate that Application Serial No. 09/313,123 is now abandoned, and that the parentheses should be deleted. These amendments are included with this response, as suggested by the Examiner.

## **III. Rejection under 35 U.S.C. § 101**

Claims 42 and 46 were rejected under 35 U.S.C. § 101 as being allegedly directed to non-statutory subject matter.

The Examiner suggested amending claim 42 to recite "An isolated or recombinant nucleic acid". Claim 42 has been so amended in this response.

The Examiner noted that there is no indication that the plant of claim 46 is produced by the hand of man, and that it reads on a product of nature. Claim 46 has been amended to indicate that the plant is transgenic, and not a product of nature.

#### IV. Rejection under 35 U.S.C. § 112, second paragraph

Claims 42-46 were rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite in claiming the subject matter of the invention.

1. The Examiner indicated that the limitations “at amino acid position 447” and “at amino acid position 481” in claims 42-46 are relative limitations which render the claims indefinite.

Applicants are unclear as to why a specified amino acid position of a threonine deaminase protein is relative or indefinite. Example 1 at pages 145-151 describe the design, preparation, and testing of nucleic acid sequences and their encoded threonine deaminase proteins, wherein the encoded amino acid residues at positions 447 and/or 481 have been changed.

Amino acid positions are commonly used by those of skill in the art to refer to particular locations within a protein or peptide sequence. Amino acid numbering starts at the N-terminus of the protein or peptide, and increases by one with each additional amino acid residue (i.e. the amino acid at the N-terminus is position 1, the next amino acid is position 2, and so on). This information on amino acid position numbering can be found in all basic biochemistry textbooks. Applicants have not proposed a different numbering system, or a protein with a different number of amino acids. The claims at each instance refer to the amino acid number relative to the wild type protein, i.e., the amino acid sequence found in nature.

Applicants assert that the language of claims 42-46 would be clear to one of ordinary skill in the art, either alone or in combination with the disclosure of the instant specification. Applicants would appreciate any alternative language that the Examiner can suggest that may be more definite.

2. The Examiner indicated that the phrase “effective to catalyze the conversion of threonine to  $\alpha$ -ketobutyrate” in claims 42-46 render the claims indefinite as it is unclear what the metes and bounds of “effective” are.

The phrase “a threonine deaminase protein effective to catalyze the conversion of threonine to  $\alpha$ -ketobutyrate” has been changed to --a threonine deaminase protein capable of catalyzing the conversion of threonine to  $\alpha$ -ketobutyrate--. Applicants assert that this language now clearly and unambiguously refers to a functional property of the protein. That is, this property flows necessarily from the amino acid sequence of the protein and is not an additional claim limitation to be met by some unstated or ambiguous means. The metes and bounds of the claimed subject matter – by which a person of ordinary skill determines whether or not the claim is infringed – are entirely defined by the structural limitations of the claims, which relate to the amino acid sequence of the protein relative to the wild type.

3. The Examiner found claim 44 to be indefinite as it is unclear if the claimed recombinant host cell has been transformed with a nucleic acid encoding a threonine deaminase protein, or if it inherently comprises the protein with the claimed properties.

Claim 44 has been amended to indicate that the threonine deaminase protein has an amino acid sequence that is a variant relative to the wild-type protein that would be present naturally in a cell of the same species. This is consistent with the disclosure of the instant specification. This is also consistent with method claim 45, wherein host cells are transformed with a recombinant vector to produce recombinant host cells.

4. The Examiner found claim 46 to be indefinite as it is unclear if the claimed plant has been transformed with a nucleic acid encoding a threonine deaminase protein, or if it inherently comprises the protein with the claimed properties.

Claim 46 has been amended to reflect that the wild-type protein does not comprise the particular amino acid sequence claimed. This is consistent with the disclosure of the instant specification. For example, at page 12, lines 5-6 and 15-18, the specification describes a plant having a genome comprising introduced DNAs, and that cells of the plant produce an elevated amount of threonine compared to cells of a corresponding, wild-type plant not comprising the introduced DNAs.

Applicants respectfully request that the rejections of claims 42-46 under 35 U.S.C. § 112, second paragraph be withdrawn.

#### **V. Rejection under 35 U.S.C. § 102**

1. Claims 42-45 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Samach et al. (*Proc. Natl. Acad. Sci. U.S.A.* 88: 2678-2682 (1991); hereinafter “Samach”).

The Examiner indicated that Samach disclosed a nucleic acid isolated from *Lycopersicon esculentum* encoding a threonine deaminase protein. The protein contains a valine at position 481 relative to the *E. coli* threonine deaminase protein, and it catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate. Samach further disclosed a recombinant vector, a recombinant host cell, and a method of preparing recombinant host cells.

The pending claims have been amended to remove valine as one of the possible amino acids at position 481. Accordingly, Samach does not teach all of the elements of claims 42-45, and does not anticipate the claims.

2. Claims 42-46 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Colau et al. (*Molecular and Cellular Biology* 7(7): 2552-2557 (1987); hereinafter “Colau”).

The Examiner indicated that Colau discloses a nucleic acid isolated from *Saccharomyces cerevisiae* encoding a threonine deaminase protein. The protein contains a valine at position 481 relative to the *E. coli* threonine deaminase protein, and it catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate. Colau further disclosed a recombinant vector, a recombinant host cell, a method of preparing recombinant host cells, and a transformed plant.

The pending claims have been amended to remove valine as one of the possible amino acids at position 481. Accordingly, Colau does not teach all of the elements of claims 42-46, and does not anticipate the claims.

3. Claims 42-45 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hashiguchi et al. (U.S. Patent No. 5,998,178; published December 7, 1999, filed May 26, 1995; hereinafter "Hashiguchi").

The Examiner indicated that Hashiguchi disclosed a nucleic acid isolated from *E. coli* encoding a threonine deaminase protein. The protein contains a proline at position 447 relative to the *E. coli* threonine deaminase protein (column 3, second paragraph, and SEQ ID NO:1), and it catalyzes the conversion of threonine to  $\alpha$ -ketobutyrate. Hashiguchi further disclosed a recombinant vector, a recombinant host cell, and a method of preparing recombinant host cells.

The pending claims have been amended to remove proline as one of the possible amino acids at position 447. Accordingly, Hashigushi does not teach all of the elements of claims 42-45, and does not anticipate the claims.

Applicants respectfully request that the rejections of claims 42-46 under 35 U.S.C. § 102 be withdrawn.

## **VI. Rejection under doctrine of double patenting**

Claims 42-46 were rejected under the judicially created doctrine of obvious-type double patenting over claims 1, 7, and 19 of U.S. Patent No. 5,942,660. Applicants note that the '660 patent is related to the instant patent application, and is commonly owned. Enclosed is a terminal disclaimer to overcome the double patenting rejection.

\* \* \* \* \*

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicants respectfully submit that no amendments have been made to the pending claims for the purpose of overcoming any prior art rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Christopher J. Buntel', with a stylized flourish extending to the right.

Christopher J. Buntel, Ph.D.

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